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Dentistry — Digital impression devices —

Part 1: Methods for assessing accuracy

Médecine bucco-dentaire — Dispositifs d'empreinte numérique —

Partie 1: Méthodes d'évaluation de l'exactitude

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM Systems*.

A list of all parts in the ISO 20896 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Dental CAD/CAM systems that produce indirect dental restorations require a three dimensional digitized description, often called a digital impression, of a patient's dentition as a starting point for the design and fabrication of inlays, crowns, bridges and larger fixed or removable appliances. The device that digitizes the three dimensional surface shall be sufficiently accurate to enable the design and manufacture of a clinically acceptable restoration.

This document describes test methods for evaluating the accuracy of digitizing devices that acquire data by direct scanning of a patient's dentition with a manually guided; that is hand-held, device in order to obtain a digital impression. A companion document, ISO 12836, provides test methods for assessing the accuracy of fixed devices for digitizing physical impressions or models cast from such impressions. Separate standards were deemed necessary after it became apparent that two of the test objects described in ISO 12836 are unsuited for successful interpretation of data acquired from these objects with a hand-held scanning device.

NOTE Testing conducted outside the oral cavity on objects that are ideal – in having both surface characteristics suitable for a given scanning technology and sufficient recognizable features for registration algorithms to function well – will give a better result than can be achieved under less ideal, clinical conditions.

Dentistry — Digital impression devices —

Part 1:
Methods for assessing accuracy

1 Scope

This document specifies test methods and procedures for assessing the accuracy of a three dimensional numerical description of intra-oral surfaces acquired directly from a patient with a hand-held scanning device. The test methods are not applicable to ultrasonic, radiographic or magnetic resonance imaging methods.

NOTE ISO 12836 specifies the test methods for the assessment of accuracy of digitizing devices that use a fixed or a mechanically guided scanning device.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 6873:2013, *Dentistry — Gypsum products*

ISO 18739:2016, *Dentistry — Vocabulary of process chain for CAD/CAM systems*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

ISO 22112, *Dentistry — Artificial teeth for dental prostheses*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

3 Terms and definitions

For the purposes of this document, the terms and definitions from ISO 1942, ISO 3534-1, ISO 5725-1, ISO 18739, ISO/IEC Guide 99, ISO/IEC Guide 98-3, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accuracy
closeness of agreement between a test result and an accepted reference value

[SOURCE: ISO 18739:2016, 3.2.1]

Note 1 to entry: Accuracy is a qualitative concept. For the purpose of this document accuracy is to be expressed as specified in 5.4.3.

3.2
bias
expectation of the difference between test results and an accepted reference value

[SOURCE: ISO 3534-1:2006, 1.33, modified to specify test results and reference value]

Note 1 to entry: For the purpose of this document bias is to be expressed as given in 5.4.2.

3.3
digital impression
acquisition of a data set with the numerical three dimensional representation of the surfaces from the patient directly, or the outcome of such an acquisition

[SOURCE: ISO 18739:2016, 3.1.20, modified]

Note 1 to entry: This definition extends ISO 18739:2016, 3.1.20 to include the outcome of data acquisition.

Note 2 to entry: A digital impression may be supplemented by data on surface colour.

Note 3 to entry: A digital impression is distinct from a virtual model as defined in ISO 18739:2016, 3.1.40. A virtual model is the graphical output from design or similar software; a digital impression is the input to this software.

3.4
digital impression device
combination of a *hand-held scanning device* (3.6) suited for use in the oral cavity, and computer hardware and software that outputs a numerical, three dimensional description of scanned surfaces

3.5
dimension of interest
distance between features of a test object that are required to be both measured independently as a reference or true value and estimated by the *digital impression device* (3.4) using a prescribed *scanning procedure* (3.12)

3.6
hand-held scanning device
camera or similar sensor which may be moved freely as it captures light reflected or diffusely scattered from a surface and converts it into a sequence of data from which *ranges* (3.9) and corresponding directions to the surface can be determined

Note 1 to entry: The instrument may have its own source of illumination.

Note 2 to entry: The scanning device may operate by any technology that provides data on *range* (3.9) and direction from the device to the surface.

Note 3 to entry: The values for *range* (3.9) and corresponding directions constitute the raw data for creating the *digital impression* (3.3).

3.7
observation
single item of data or of information relating items of data

Note 1 to entry: Examples of observations in intra-oral scanning are:

i) a *range* (3.9) or a component of direction in an array of digitized data,

ii) the identification of a single feature in two arrays of digitized data.

3.8
precision
closeness of agreement between independent results of measurement obtained under stipulated conditions

Note 1 to entry: Precision is a qualitative concept. The operational definition that applies in this document is the standard deviation.

[SOURCE: ISO 18739:2016, 3.2.7]

3.9
range
measured distance from the *hand-held scanning device* (3.6) to a scanned surface

3.10
registration
sub-process in analysis of scanning data in which segments of surface topography derived from data acquired by a scanning device in successive positions and orientations are aligned in order to estimate the relative translation and rotation of the scanning device

3.11
scanning pattern
sequence of translations and rotations of a *hand-held scanning device* (3.6) relative to the object being scanned as it acquires data from which to render the surface of the object as a *digital impression* (3.3)

3.12
scanning procedure
acquisition and analysis of a set of data with a *hand-held digitizing device* (3.6) according to a *scanning pattern* (3.11) for the purpose of creating a *digital impression* (3.3)

4 Requirements

4.1 General

The hand-held scanning device shall be driven by software installed in the digitizing device or by independent software specified by the manufacturer for the digitization and rendering of a digital impression of the surfaces of a patient's dentition and adjacent soft tissue.

A scanning pattern or patterns for each clinical indication described in the instructions supplied by the manufacturer shall be applied to scan the test objects described in Annex A, Annex B and Annex C for the assessment of accuracy.

If the instructions for use of a hand-held scanning device claim that it is suited to obtain a digital impression for fabricating a multi-unit fixed dental prosthesis, then two types of test object, conforming to Annex A and to Annex C shall be employed.

4.2 Reference measurement of test objects

The dimensions of interest of each test object as designated in Annex A, Annex B and Annex C shall be determined by an independent, calibrated measurement traceable to the internationally adopted standard of length. The values obtained shall be considered the true values for the dimensions of interest. The conditions of temperature and humidity under which the determination is made shall be measured and recorded.

The precision of this determination is to be expressed as standard uncertainty σ. When the precision in a true value is derived from the standard deviation S of n repeated measurements, the standard uncertainty is:

$$\sigma = S \diagup \sqrt{n}$$

where precision is obtained from a Type B evaluation of standard uncertainty as defined by ISO/IEC Guide 98-3:2008, 4.3, an appropriate conversion to standard uncertainty shall be cited.

The standard uncertainty in the reference values of the dimensions of interest shall be no greater than one-fifth of (i.e. 0.2 times) the accuracy expected, required or claimed for the digitizing device.

5 Test Methods

5.1 Test objects

5.1.1 General

The test objects described in Annex A, Annex B and Annex C, against which the results of a digitizing procedure are compared, have features for which dimensions or separations shall be determined by independent means. Such features include flat areas, linear structures, straight or curved edges and corners, or spherical markers.

The test objects may have additional decoration or incisions as necessary for successful registration and processing of the raw scanning data. Such features shall not obscure or distort surfaces required for measuring the defined dimensions of interest.

The test object shall be uniquely identified by a permanent label.

5.1.2 Preparation

The test object shall be fabricated and prepared for scanning as described below before calibration and the dimensions of interest are determined.

The surfaces of the test objects described in Annex A and Annex B and the gauge spheres described in Annex C may be rendered light-diffusing by sand-blasting or similar treatment. The surface roughness amplitude shall be measured and recorded. Treatment shall be carried out prior to measurement of reference values.

Surfaces may be coated or sprayed.

If required in order for the registration stage of data processing to function, the surfaces of the test objects described in Annex A and Annex B may be decorated or incised with details that break the mirror and cylindrical symmetries of the test objects. There shall remain sufficient undecorated and un-incised area to allow complete determination of the upper and lower circumferences of the cone or conical hole, and to determine the planes of the upper and lower surfaces of the test object.

5.1.3 Measurement of reference values

The apparatus employed for the independent measurement of dimensions of interest shall be traceably calibrated to the internationally adopted standard of length to ensure compliance with the accuracy and precision required by 4.2.

The test object or objects shall be measured and the reference values shall be recorded prior to their use to assess accuracy of a scanning device. The reference values shall be those of the test object without surface spray or coating.

NOTE For any test object created from a material that could have dimensional instability, a re-measurement of the reference values of the dimensions of interest is recommended after the assessment measurements have been performed.

5.2 Test conditions

5.2.1 Ambient conditions

The scanning device shall be evaluated under ambient conditions. The temperature and relative humidity during measurement shall be measured and recorded.

5.2.2 Scanning pattern

The scanning pattern, including the orientation of the hand-held scanning device, shall reflect the restrictions that the oral cavity would impose in clinical use.

The scanning device shall be moved freely by hand in accordance with the scanning pattern without mechanical guidance.

5.2.3 Scanning time

Testing procedures should be completed in an efficient manner typical for the clinical use for which it is intended. The time taken to complete each scan of a test object should be recorded.

5.2.4 Number of scans

At least 30 (n = 30) scanning procedures shall be performed on a test object and a digital impression obtained and measured for each procedure.

Only if an individual scanning procedure fails during acquisition or processing so that a digital impression is not produced, or is not suitable for estimation of the dimensions of interest, shall that procedure be discarded.

5.3 Processing of the digital impression

5.3.1 General

The dimensions of interest shall be extracted from the digital impression by software supplied with the digitizing device. Only if the digitizing device lacks this functionality shall the dimensions of interest be extracted from the digital impression by independent software.

5.3.2 Dimensions of interest

The analysis software of the digital impression device shall be used to analyse each digital impression as required. If the device's own software does not have this functionality, independent software shall be used to analyse each digital impression.

5.3.3 Determination of dimensions

After the execution of a scanning procedure, the value of each dimension of interest shall be determined from the digital impression and recorded.